Carrie Dunford, PharmD; Pharmacy Board Member, presented an edited version of The Controlled Substance Database Act: UCA §§ 58-37f to the Pharmacy Board and to the Division for review and comment. On 10/22/2019. The Board unanimously approved Dr. Dunford's edits and requested the Division to move forward with providing the edited document to a legislative analyst for review and analysis for future legislative consideration. Below is said document with edits.

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Chapter 37f

Controlled Substance Database Act

Part 1

General Provisions

58-37f-101 Title.

This chapter is known as the "Controlled Substance Database Act."

Enacted by Chapter 287, 2010 General Session

58-37f-102 Definitions.

- (1) The definitions in Section 58-37-2 apply to this chapter.
- (2) As used in this chapter:
- (a) "Board" means the Utah State Board of Pharmacy created in Section 58-17b-201.
- (b) "Business associate" is as defined under the HIPAA privacy, security, and breach notification rules in 45 C.F.R. 164.502(a), 164.504(e), and 164.532(d) and (e).
- (c) "Database" means the controlled substance database created in Section 58-37f-201.
- (d) "De-identified" is as defined in 45 C.F.R. 164.502(d) and 164.514(a), (b), and (c).
- (e) "Health care facility" is as defined in Section 26-21-2.
- (f) "Mental health therapist" is as defined in Section 58-60-102.
- (g) "Pharmacy" or "pharmaceutical facility" is as defined in Section 58-17b-102.
- (h) "Prospective patient" means an individual who:
- (i) is seeking medical advice, medical treatment, or medical services from a practitioner; and
- (ii) the practitioner described in Subsection (2)(h)(i) is considering accepting as a patient.
- (i) "Substance abuse treatment program" is as defined in Section 62A-2-101.

Amended by Chapter 130, 2013 General Session

Part 2

Controlled Substance Database

58-37f-201 Controlled substance database -- Creation -- Purpose.

- (1) There is created within the division a controlled substance database.
- (2) The division shall administer and direct the functioning of the database in accordance with this chapter.
- (3) The division may, under state procurement laws, contract with another state agency or a private entity to establish, operate, or maintain the database.
- (4) The division shall, in collaboration with the board, determine whether to operate the database within the division or contract with another entity to operate the database, based on an analysis of costs and benefits.
- (5) The purpose of the database is to contain:
- (a) the data described in Section 58-37f-203 regarding every prescription for a controlled substance dispensed in the state to any individual other than an inpatient in a licensed health care facility;
- (b) data reported to the division under Section 26-21-26 regarding poisoning or overdose; Utah Code

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- (c) data reported to the division under Subsection 41-6a-502(4) or 41-6a-502.5(5)(b) regarding convictions for driving under the influence of a prescribed controlled substance or impaired driving; and
- (d) data reported to the division under Subsection 58-37-8(1)(e) or 58-37-8(2)(j) regarding certain violations of the Utah Controlled Substances Act.
- (6) The division shall maintain the database in an electronic file or by other means established by the division to facilitate use of the database for identification of:
- (a) prescribing practices and patterns of prescribing and dispensing controlled substances;
- (b) practitioners prescribing controlled substances in an unprofessional or unlawful manner;
- (c) individuals receiving prescriptions for controlled substances from licensed practitioners, and

who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance;

- (d) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to a pharmacy;
- (e) individuals admitted to a general acute hospital for poisoning or overdose involving a prescribed controlled substance; and
- (f) individuals convicted for:
- (i) driving under the influence of a prescribed controlled substance that renders the individual incapable of safely operating a vehicle;
- (ii) driving while impaired, in whole or in part, by a prescribed controlled substance; or
- (iii) certain violations of the Utah Controlled Substances Act.

Amended by Chapter 99, 2016 General Session

58-37f-202 Duties of board in relation to the database.

The board shall advise the division regarding:

- (1) establishing, maintaining, and operating the database;
- (2) access to the database and how access is obtained; and
- (3) control of information contained in the database.

Enacted by Chapter 287, 2010 General Session

58-37f-203 Submission, collection, and maintenance of data.

(1)

- (a) The division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information:
- (i) real-time submission of the information required to be submitted under this part to the controlled substance database; and
- (ii) 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database.

(b)

- (i) On and after January 1, 2016, a pharmacist shall comply with either:
- (A) the submission time requirements established by the division under Subsection (1)(a)(i);
- (B) the submission time requirements established by the division under Subsection (1)(a)(ii). Utah Code

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_(iii) Prior to January 1, 2016, a pharmacist may submit information using either option under this Subsection (1).

(c) The division shall comply with Title 63G, Chapter 6a, Utah Procurement Code.

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- (a) The pharmacist-in-charge and the pharmacist of the drug outlet where a controlled substance is dispensed shall submit the data described in this section to the division in accordance with:
- (i) the requirements of this section;
- (ii) the procedures established by the division;
- (iii) additional types of information or data fields established by the division; and
- (iv) the format established by the division.
- (b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with the provisions of this section and the dispensing medical practitioner shall assume the duties of the pharmacist under this chapter.

(3)

- (a) The pharmacist-in-charge and the pharmacist described in Subsection (2)(b) shall, for each controlled substance dispensed by a pharmacist under the pharmacist's supervision other than those dispensed administered for
- of information or data field established by the division by rule in accordance with Subsection
- (6) regarding:
- (i) each controlled substance that is dispensed by the pharmacist or under the pharmacist's supervision; and

Commented [CD1]: Remove since this date has passed?

Commented [CD2]: This is an error. There is no intent to limit this to patients who are in "inpatient" status. There are patients that are admitted to hospitals and clinics as "outpatient" status and have controlled substances administered by nurses, LIPs, or MAs working under the direction of an LIP that do not need to be reported to the database. For example, consider a patient who is admitted for a same-day surgery or a patient in an Urgent Care Clinic who is administered one dose of a controlled substance before having a dislocated joint repaired. There is no intent of this Act to have those reported.

- (ii) each noncontrolled substance that is:
- (A) designated by the division under Subsection (8)(a); and
- (B) dispensed by the pharmacist or under the pharmacist's supervision.
- (b) Subsection (3)(a) does not apply to a drug that is <u>administered</u> dispensed forto an inpatient at a health care

facility.

(4) An individual whose records are in the database may obtain those records upon submission of a written request to the division.

(5)

- (a) A patient whose record is in the database may contact the division in writing to request correction of any of the patient's database information that is incorrect. The patient shall provide a postal address for the division's response.
- (b) The division shall grant or deny the request within 30 days from receipt of the request and shall advise the requesting patient of its decision by mail postmarked within 35 days of receipt of the request.
- (c) If the division denies a request under this Subsection (5) or does not respond within 35 days, the patient may submit an appeal to the Department of Commerce, within 60 days after the postmark date of the patient's letter making a request for a correction under this Subsection (5).
- (6) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to establish submission requirements under this part, including:
- (a) electronic format;
- (b) submission procedures; and
- (c) required information and data fields.
- (7) The division shall ensure that the database system records and maintains for reference:
- (a) the identification of each individual who requests or receives information from the database;
- (b) the information provided to each individual; and

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(c) the date and time that the information is requested or provided.

(8)

- (a) The division, in collaboration with the Utah Controlled Substance Advisory Committee created in Section 58-38a-201, shall designate a list of noncontrolled substances described in Subsection (8)(b) by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act.
- (b) To determine whether a prescription drug should be designated in the schedules of controlled substances under this chapter, the division may collect information about a prescription drug as defined in Section 58-17b-102 that is not designated in the schedules of controlled substances under this chapter.

Amended by Chapter 59, 2019 General Session

Part 3

Access and Utilization

58-37f-301 Access to database.

- (1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:
- (a) effectively enforce the limitations on access to the database as described in this part; and
- (b) establish standards and procedures to ensure accurate identification of individuals requesting information or receiving information without request from the database.
- (2) The division shall make information in the database and information obtained from other state or federal prescription monitoring programs by means of the database available only to the following individuals, in accordance with the requirements of this chapter and division rules:

(a)

- (i) personnel of the division specifically assigned to conduct investigations related to controlled substance laws under the jurisdiction of the division; and
- (ii) the following law enforcement officers, but the division may only provide nonidentifying information, limited to gender, year of birth, and postal ZIP code, regarding individuals for whom a controlled substance has been prescribed or to whom a controlled substance has been dispensed:

- (A) a law enforcement agency officer who is engaged in a joint investigation with the division; and
- (B) a law enforcement agency officer to whom the division has referred a suspected criminal violation of controlled substance laws;
- (b) authorized division personnel engaged in analysis of controlled substance prescription information as a part of the assigned duties and responsibilities of their employment;
- (c) a board member if:
- (i) the board member is assigned to monitor a licensee on probation; and
- (ii) the board member is limited to obtaining information from the database regarding the specific licensee on probation;
- (d) a member of a diversion committee established in accordance with Subsection 58-1-404(2) if:
- (i) the diversion committee member is limited to obtaining information from the database regarding the person whose conduct is the subject of the committee's consideration; and Utah Code

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- (ii) the conduct that is the subject of the committee's consideration includes a violation or a potential violation of Chapter 37, Utah Controlled Substances Act, or another relevant violation or potential violation under this title;
- (e) in accordance with a written agreement entered into with the department, employees of the Department of Health:
- (i) whom the director of the Department of Health assigns to conduct scientific studies regarding the use or abuse of controlled substances, if the identity of the individuals and pharmacies in the database are confidential and are not disclosed in any manner to any individual who is not directly involved in the scientific studies;
- (ii) when the information is requested by the Department of Health in relation to a person or provider whom the Department of Health suspects may be improperly obtaining or providing a controlled substance; or
- (iii) in the medical examiner's office;
- (f) in accordance with a written agreement entered into with the department, a designee of the

director of the Department of Health, who is not an employee of the Department of Health, whom the director of the Department of Health assigns to conduct scientific studies regarding the use or abuse of controlled substances pursuant to an application process established in rule by the Department of Health, if:

- (i) the designee provides explicit information to the Department of Health regarding the purpose of the scientific studies;
- (ii) the scientific studies to be conducted by the designee:
- (A) fit within the responsibilities of the Department of Health for health and welfare;
- (B) are reviewed and approved by an Institutional Review Board that is approved for human subject research by the United States Department of Health and Human Services; and
- (C) are not conducted for profit or commercial gain; and
- (D) are conducted in a research facility, as defined by division rule, that is associated with a university or college accredited by one or more regional or national accrediting agencies recognized by the United States Department of Education;
- (iii) the designee protects the information as a business associate of the Department of Health; and
- (iv) the identity of the prescribers, patients, and pharmacies in the database are de-identified, confidential, not disclosed in any manner to the designee or to any individual who is not directly involved in the scientific studies;
- (g) in accordance with the written agreement entered into with the department and the Department of Health, authorized employees of a managed care organization, as defined in 42 C.F.R. Sec. 438, if:
- (i) the managed care organization contracts with the Department of Health under the provisions of Section 26-18-405 and the contract includes provisions that:
- (A) require a managed care organization employee who will have access to information from the database to submit to a criminal background check; and
- (B) limit the authorized employee of the managed care organization to requesting either the division or the Department of Health to conduct a search of the database regarding a specific Medicaid enrollee and to report the results of the search to the authorized

employee; and

(ii) the information is requested by an authorized employee of the managed care organization in relation to a person who is enrolled in the Medicaid program with the managed care organization, and the managed care organization suspects the person may be improperly obtaining or providing a controlled substance;

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(h) a licensed practitioner having authority to prescribe controlled substances, to the extent the information:

(i)

- (A) relates specifically to a current or prospective patient of the practitioner; and
- (B) is provided to or sought by the practitioner for the purpose of:
- (I) prescribing or considering prescribing any controlled substance to the current or prospective patient;
- (II) diagnosing the current or prospective patient;
- (III) providing medical treatment or medical advice to the current or prospective patient; or
- (IV) determining whether the current or prospective patient:
- (Aa) is attempting to fraudulently obtain a controlled substance from the practitioner; or
- (Bb) has fraudulently obtained, or attempted to fraudulently obtain, a controlled substance from the practitioner;

(ii)

- (A) relates specifically to a former patient of the practitioner; and
- (B) is provided to or sought by the practitioner for the purpose of determining whether the former patient has fraudulently obtained, or has attempted to fraudulently obtain, a controlled substance from the practitioner;
- (iii) relates specifically to an individual who has access to the practitioner's Drug Enforcement Administration identification number, and the practitioner suspects that the individual may have used the practitioner's Drug Enforcement Administration identification number to fraudulently acquire or prescribe a controlled substance;

- (iv) relates to the practitioner's own prescribing practices, except when specifically prohibited by the division by administrative rule;
- (v) relates to the use of the controlled substance database by an employee of the practitioner, described in Subsection (2)(i); or
- (vi) relates to any use of the practitioner's Drug Enforcement Administration identification number to obtain, attempt to obtain, prescribe, or attempt to prescribe, a controlled substance;
- (i) in accordance with Subsection (3)(a), an employee of a practitioner described in Subsection
- (2)(h), for a purpose described in Subsection (2)(h)(i) or (ii), if:
- (i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;
- (ii) the practitioner provides written notice to the division of the identity of the employee; and (iii) the division:
- (A) grants the employee access to the database; and
- (B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(5) with respect to the employee;
- (j) an employee of the same business that employs a licensed practitioner under Subsection (2) (h) if:
- (i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;
- (ii) the practitioner and the employing business provide written notice to the division of the identity of the designated employee; and
- (iii) the division:
- (A) grants the employee access to the database; and

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(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection

58-37f-203(5) with respect to the employee;

(k) a licensed pharmacist having authority to dispense a controlled substance, or a licensed pharmacy intern, or pharmacy technician working under the general supervision of a licensed pharmacist to the extent the

information is provided or sought for the purpose of:

- (i) dispensing or considering dispensing any controlled substance; or
- (ii) determining whether a person:
- (A) is attempting to fraudulently obtain a controlled substance from the pharmacistpharmacy, practitioner, or health care facility; or
- (B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled substance from the pharmacy, practitioner, or health care facilityist;
- (iii) reporting to the controlled substance database; or

(iv) verifying the accuracy of the data submitted to the controlled substance database on behalf of a pharmacy where the licensed pharmacist, pharmacy intern, or pharmacy technician is employed.

_(I) in accordance with Subsection (3)(a), a licensed pharmacy technician and pharmacy intern who is an employee of a pharmacy as defined in Section 58-17b-102, for the purposes described in Subsection (2)(j)(i) or (ii), if:

(i) the employee is designated by the pharmacist-in-charge as an individual authorized to access the information on behalf of a licensed pharmacist employed by the pharmacy;

(ii) the pharmacist in charge provides written notice to the division of the identity of the employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(5) with respect to the employee;

- (m) pursuant to a valid search warrant, federal, state, and local law enforcement officers and state and local prosecutors who are engaged in an investigation related to:
- (i) one or more controlled substances; and
- (ii) a specific person who is a subject of the investigation;

- (n) subject to Subsection (7), a probation or parole officer, employed by the Department of Corrections or by a political subdivision, to gain access to database information necessary for the officer's supervision of a specific probationer or parolee who is under the officer's direct supervision;
- (o) employees of the Office of Internal Audit and Program Integrity within the Department of Health who are engaged in their specified duty of ensuring Medicaid program integrity under Section 26-18-2.3;
- (p) a mental health therapist, if:
- (i) the information relates to a patient who is:
- (A) enrolled in a licensed substance abuse treatment program; and
- (B) receiving treatment from, or under the direction of, the mental health therapist as part of the patient's participation in the licensed substance abuse treatment program described in Subsection (2)(p)(i)(A);
- (ii) the information is sought for the purpose of determining whether the patient is using a controlled substance while the patient is enrolled in the licensed substance abuse treatment program described in Subsection (2)(p)(i)(A); and
- (iii) the licensed substance abuse treatment program described in Subsection (2)(p)(i)(A) is associated with a practitioner who:
- (A) is a physician, a physician assistant, an advance practice registered nurse, or a pharmacist; and
- (B) is available to consult with the mental health therapist regarding the information obtained by the mental health therapist, under this Subsection (2)(p), from the database;

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- (q) an individual who is the recipient of a controlled substance prescription entered into the database, upon providing evidence satisfactory to the division that the individual requesting the information is in fact the individual about whom the data entry was made;
- (r) an individual under Subsection (2)(q) for the purpose of obtaining a list of the persons and entities that have requested or received any information from the database regarding the

individual, except if the individual's record is subject to a pending or current investigation as authorized under this Subsection (2);

- (s) the inspector general, or a designee of the inspector general, of the Office of Inspector General of Medicaid Services, for the purpose of fulfilling the duties described in Title 63A, Chapter 13, Part 2, Office and Powers;
- (t) the following licensed physicians for the purpose of reviewing and offering an opinion on an individual's request for workers' compensation benefits under Title 34A, Chapter 2, Workers' Compensation Act, or Title 34A, Chapter 3, Utah Occupational Disease Act:
- (i) a member of the medical panel described in Section 34A-2-601;
- (ii) a physician employed as medical director for a licensed workers' compensation insurer or an approved self-insured employer; or
- (iii) a physician offering a second opinion regarding treatment; and
- (u) members of Utah's Opioid Fatality Review Committee, for the purpose of reviewing a specific fatality due to opioid use and recommending policies to reduce the frequency of opioid use fatalities.
- (3)
- (a)
- (i) A practitioner described in Subsection (2)(h) may designate one or more employees to access information from the database under Subsection (2)(i), (2)(j), or (4)(c).
- _(iii) A pharmacist described in Subsection (2)(k) who is a pharmacist in charge may designate up to five employees to access information from the database under Subsection (2)(I).
- (b) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:
- (i) establish background check procedures to determine whether an employee designated under Subsection (2)(i), (2)(j), or (4)(c) should be granted access to the database; and
- (ii) establish the information to be provided by an emergency department employee under Subsection (4); and
- (iii) facilitate providing controlled substance prescription information to a third party under Subsection (5).

(c) The division shall grant an employee designated under Subsection (2)(i), (2)(j), or (4)(c) access to the database, unless the division determines, based on a background check, that the employee poses a security risk to the information contained in the database.

(4)

- (a) An individual who is employed in the emergency department of a hospital may exercise access to the database under this Subsection (4) on behalf of a licensed practitioner if the individual is designated under Subsection (4)(c) and the licensed practitioner:
- (i) is employed or privileged to work in the emergency department;
- (ii) is treating an emergency department patient for an emergency medical condition; and (iii) requests that an individual employed in the emergency department and designated under Subsection (4)(c) obtain information regarding the patient from the database as needed in the course of treatment.
- (b) The emergency department employee obtaining information from the database shall, when gaining access to the database, provide to the database the name and any additional Utah Code

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identifiers regarding the requesting practitioner as required by division administrative rule established under Subsection (3)(b).

- (c) An individual employed in the emergency department under this Subsection (4) may obtain information from the database as provided in Subsection (4)(a) if:
- (i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;
- (ii) the practitioner and the hospital operating the emergency department provide written notice to the division of the identity of the designated employee; and
- (iii) the division:
- (A) grants the employee access to the database; and
- (B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(5) with respect to the employee.

Commented [CD3]: Many ED physicians are not specifically employed by the hospital and are essentially privileged to work at the facility as an independent contractor.

(5)

(a)

- (i) An individual may request that the division provide the information under Subsection (5)
- (b) to a third party who is designated by the individual each time a controlled substance prescription for the individual is dispensed.
- (ii) The division shall upon receipt of the request under this Subsection (5)(a) advise the individual in writing that the individual may direct the division to discontinue providing the information to a third party and that notice of the individual's direction to discontinue will be provided to the third party.
- (b) The information the division shall provide under Subsection (5)(a) is:
- (i) the fact a controlled substance has been dispensed to the individual, but without identifying the controlled substance; and
- (ii) the date the controlled substance was dispensed.

(c)

- (i) An individual who has made a request under Subsection (5)(a) may direct that the division discontinue providing information to the third party.
- (ii) The division shall:
- (A) notify the third party that the individual has directed the division to no longer provide information to the third party; and
- (B) discontinue providing information to the third party.

(6)

- (a) An individual who is granted access to the database based on the fact that the individual is a licensed practitioner or a mental health therapist shall be denied access to the database when the individual is no longer licensed.
- (b) An individual who is granted access to the database based on the fact that the individual is a

designated employee of a licensed practitioner shall be denied access to the database when the practitioner is no longer licensed.

(7) A probation or parole officer is not required to obtain a search warrant to access the database in accordance with Subsection (2)(n).

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- (8) The division shall review and adjust the database programming which automatically logs off an individual who is granted access to the database under Subsections (2)(h), (2)(i), (2)(j), and (4)
- (c) to maximize the following objectives:
- (a) to protect patient privacy;
- (b) to reduce inappropriate access; and
- (c) to make the database more useful and helpful to a person accessing the database under Subsections (2)(h), (2)(i), (2)(j), and (4)(c), especially in high usage locations such as an emergency department.

Amended by Chapter 123, 2018 General Session

58-37f-302 Other restrictions on access to database.

- (1) A person who is a relative of a deceased individual is not entitled to access information from the database relating to the deceased individual based on the fact or claim that the person is:
- (a) related to the deceased individual; or
- (b) subrogated to the rights of the deceased individual.
- (2) Except as provided in Subsection (3), data provided to, maintained in, or accessed from the database that may be identified to, or with, a particular person is not subject to discovery, subpoena, or similar compulsory process in any civil, judicial, administrative, or legislative proceeding, nor shall any individual or organization with lawful access to the data be compelled to testify with regard to the data.
- (3) The restrictions described in Subsection (2) do not apply to a civil, judicial, or administrative action brought to enforce the provisions of this chapter.

Enacted by Chapter 287, 2010 General Session

58-37f-303 Access to opioid prescription information via an electronic data system.

- (1) As used in this section:
- (a) "Dispense" means the same as that term is defined in Section 58-17b-102.
- (b) "EDS user":
- (i) means:
- (A) a prescriber;
- (B) a pharmacist; or
- (C) a pharmacy intern; or
- (D) a pharmacy technician; or
- (C) an individual granted access to the database under Subsection 58-37f-301(3)(c); and
- (ii) does not mean an individual whose access to the database has been revoked by the division pursuant to Subsection 58-37f-301(5)(b).
- (c) "Electronic data system" means a software product or an electronic service used by:
- (i) a prescriber to manage electronic health records; or
- (ii) a pharmacist, pharmacy intern, or pharmacy technician working under the general supervision of a licensed pharmacist to manage the dispensing of prescription drugs.
- (d) "Opioid" means any substance listed in Subsection 58-37-4(2)(b)(i) or (2)(b)(ii).
- (e) "Pharmacist" means the same as that term is defined in Section 58-17b-102.
- (f) "Prescriber" means a practitioner, as that term is defined in Section 58-37-2, who is licensed under Section 58-37-6 to prescribe an opioid.
- (g) "Prescription drug" means the same as that term is defined in Section 58-17b-102.
- (2) Subject to Subsections (3) through (6), no later than January 1, 2017, the division shall make opioid prescription information in the database available to an EDS user via the user's electronic data system.

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(3) An electronic data system may be used to make opioid prescription information in the database available to an EDS user only if the electronic data system complies with rules established by the division under Subsection (4).

(4)

Commented [CD4]: Do I need to add definitions for pharmacy intern and Pharmacy technician?

- (a) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, specifying:
- (i) an electronic data system's:
- (A) allowable access to and use of opioid prescription information in the database; and
- (B) minimum actions that must be taken to ensure that opioid prescription information accessed from the database is protected from inappropriate disclosure or use; and (ii) an EDS user's:
- (A) allowable access to opioid prescription information in the database via an electronic data system; and
- (B) allowable use of the information.
- (b) The rules shall establish:
- (i) minimum user identification requirements that in substance are the same as the database identification requirements in Section 58-37f-301;
- (ii) user access restrictions that in substance are the same as the database identification requirements in Section 58-37f-301; and
- (iii) any other requirements necessary to ensure that in substance the provisions of Sections 58-37f-301 and 58-37f-302 apply to opioid prescription information in the database that has been made available to an EDS user via an electronic data system.
- (5) The division may not make opioid prescription information in the database available to an EDS user via the user's electronic data system if:
- (a) the electronic data system does not comply with the rules established by the division under Subsection (4); or
- (b) the EDS user does not comply with the rules established by the division under Subsection (4).
- (6)
- (a) The division shall periodically audit the use of opioid prescription information made available to an EDS user via the user's electronic data system.
- (b) The audit shall review compliance by:
- (i) the electronic data system with rules established by the division under Subsection (4); and
- (ii) the EDS user with rules established by the division under Subsection (4).

(c)

- (i) If the division determines by audit or other means that an electronic data system is not in compliance with rules established by the division under Subsection (4), the division shall immediately suspend or revoke the electronic data system's access to opioid prescription information in the database.
- (ii) If the division determines by audit or other means that an EDS user is not in compliance with rules established by the division under Subsection (4), the division shall immediately suspend or revoke the EDS user's access to opioid prescription information in the database via an electronic data system.
- (iii) If the division suspends or revokes access to opioid prescription information in the database under Subsection (6)(c)(i) or (6)(c)(ii), the division shall also take any other appropriate corrective or disciplinary action authorized by this chapter or title.

Enacted by Chapter 112, 2016 General Session

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58-37f-304 Database utilization.

- (1) As used in this section:
- (a) "Dispenser" means a licensed pharmacist, as described in Section 58-17b-303, or the pharmacist's licensed intern, or licensed pharmacy technician working under the supervision of a licensed pharmacist as described in Section 58-17b-304, who is also licensed to

dispense a controlled substance under Title 58, Chapter 37, Utah Controlled Substances Act.

- (b) "Outpatient" means a setting in which an individual visits a licensed healthcare facility or a healthcare provider's office for a diagnosis or treatment but is not admitted to a licensed healthcare facility for an overnight stay.
- (c) "Prescriber" means an individual authorized to prescribe a controlled substance under Title 58, Chapter 37, Utah Controlled Substances Act.
- (d) "Schedule II opioid" means those substances listed in Subsection 58-37-4(2)(b)(i) or (2)(b)(ii).
- (e) "Schedule III opioid" means those substances listed in Subsection 58-37-4(2)(c) that are opioids.

(2)

- (a) A prescriber shall check the database for information about a patient before the first time the prescriber gives a prescription to a patient for a Schedule II opioid or a Schedule III opioid.
- (b) If a prescriber is repeatedly prescribing a Schedule II opioid or Schedule III opioid to a patient, the prescriber shall periodically review information about the patient in:
- (i) the database; or
- (ii) other similar records of controlled substances the patient has filled.
- (c) A prescriber may assign the access and review required under Subsection (2)(a) to one or more employees in accordance with Subsections 58-37f-301(2)(i) and (j).

(d)

- (i) A prescriber may comply with the requirements in Subsections (2)(a) and (b) by checking an electronic health record system if the electronic health record system:
- (A) is connected to the database through a connection that has been approved by the division; and
- (B) displays the information from the database in a prominent manner for the prescriber.
- (ii) The division may not approve a connection to the database if the connection does not satisfy the requirements established by the division under Section 58-37f-301.
- (e) A prescriber is not in violation of the requirements of Subsection (2)(a) or (b) if the failure to comply with Subsection (2)(a) or (b):
- (i) is necessary due to an emergency situation;
- (ii) is caused by a suspension or disruption in the operation of the database; or
- (iii) is caused by a failure in the operation or availability of the Internet.
- (f) The division may not take action against the license of a prescriber for failure to comply with this Subsection (2) unless the failure occurs after the earlier of:
- (i) December 31, 2018; or
- (ii) the date that the division has the capability to establish a connection that meets the requirements established by the division under Section 58-37f-301 between the database and an electronic health record system.
- (3) The division shall, in collaboration with the licensing boards for prescribers and dispensers:

- (a) develop a system that gathers and reports to prescribers and dispensers the progress and results of the prescriber's and dispenser's individual access and review of the database, as provided in this section; and
- (b) reduce or waive the division's continuing education requirements regarding opioid prescriptions, described in Section 58-37-6.5, including the online tutorial and test relating to Utah Code

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the database, for prescribers and dispensers whose individual utilization of the database, as determined by the division, demonstrates substantial compliance with this section.

(4) If the dispenser's access and review of the database suggest that the individual seeking an opioid may be obtaining opioids in quantities or frequencies inconsistent with generally recognized standards as provided in this section and Section 58-37f-201, the dispenser shall reasonably attempt to contact the prescriber to obtain the prescriber's informed, current, and professional decision regarding whether the prescribed opioid is medically justified, notwithstanding the results of the database search.

(5)

- (a) The division shall review the database to identify any prescriber who has a pattern of prescribing opioids not in accordance with the recommendations of:
- (i) the CDC Guideline for Prescribing Opioids for Chronic Pain, published by the Centers for Disease Control and Prevention;
- (ii) the Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, published by the Department of Health; or
- (iii) other publications describing best practices related to prescribing opioids as identified by division rule in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, and in consultation with the Physicians Licensing Board.
- (b) The division shall offer education to a prescriber identified under this Subsection (5) regarding best practices in the prescribing of opioids.
- (c) A decision by a prescriber to accept or not accept the education offered by the division under this Subsection (5) is voluntary.

- (d) The division may not use an identification the division has made under this Subsection (5) or the decision by a prescriber to accept or not accept education offered by the division under this Subsection (5) in a licensing investigation or action by the division.
- (e) Any record created by the division as a result of this Subsection (5) is a protected record under Section 63G-2-305.
- (6) The division may consult with a prescriber or health care system to assist the prescriber or health care system in following evidence-based guidelines regarding the prescribing of controlled substances, including the recommendations listed in Subsection (5)(a).

Amended by Chapter 128, 2019 General Session

Part 4

Registration and Training

58-37f-401 Database registration required -- Penalties for failure to register.

(1) Each individual, other than a veterinarian, who, on June 30, 2010, has a license to prescribe a controlled substance under Chapter 37, Utah Controlled Substances Act, but is not registered with the division to use the database shall, on or before September 30, 2010, register with the division to use the database.

(2)

(a) An individual who is not a veterinarian, who obtains a new license to prescribe a controlled substance under Chapter 37, Utah Controlled Substances Act, shall, within 30 days after the day on which the individual obtains a license to prescribe a controlled substance from the Drug Enforcement Administration, register with the division to use the database.

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- (b) An individual who is not a veterinarian may not renew a license to prescribe a controlled substance under Chapter 37, Utah Controlled Substances Act, unless the individual registers with the division to use the database.
- (3) Beginning on November 2, 2012, in order to register to use the database, the individual registering must participate in the online tutorial and pass the online test described in Section 58-37f-402.

- (4) Failure by an individual to comply with the requirements of this section is grounds for the division to take the following actions in accordance with Section 58-1-401:
- (a) refuse to issue a license to the individual;
- (b) refuse to renew the individual's license; or
- (c) revoke, suspend, restrict, or place on probation the license.
- (5) Beginning on July 1, 2010, the division shall, in accordance with Section 63J-1-504, impose an annual database registration fee on an individual who registers to use the database, to pay the startup and ongoing costs of the division for complying with the requirements of this section.

 Amended by Chapter 318, 2018 General Session
- 58-37f-402 Online tutorial and test relating to the database -- Fees -- Rulemaking authority -- Continuing professional education credit.
- (1) The division shall develop an online tutorial and an online test for registration to use the database that provides instruction regarding, and tests, the following:
- (a) the purpose of the database;
- (b) how to access and use the database;
- (c) the law relating to:
- (i) the use of the database; and
- (ii) the information submitted to, and obtained from, the database; and
- (d) basic knowledge that is important for all people who prescribe controlled substances to know in order to help ensure the health and safety of an individual to whom a controlled substance is prescribed.
- (2) The division shall design the test described in this section as follows:
- (a) an individual shall answer all of the questions correctly in order to pass the test;
- (b) an individual shall be permitted to immediately retake the portion of the test that the individual answers incorrectly as many times as necessary for the individual to pass the test; and
- (c) after an individual takes the test, the test software shall:
- (i) immediately inform the individual of the number of questions that were answered incorrectly;
- (ii) provide the correct answers;
- (iii) replay the portion of the tutorial that relates to the incorrectly answered questions; and

- (iv) ask the individual the incorrectly answered questions again.
- (3) The division shall design the tutorial and test so that it is possible to take the tutorial and complete the test in 20 minutes or less, if the individual answers all of the questions correctly on the first attempt.
- (4) The division shall ensure that the tutorial and test described in this section are fully functional and available for use online on or before November 1, 2010.
- (5) The division shall impose a fee, in accordance with Section 63J-1-504, on an individual who takes the test described in this section, to pay the costs incurred by the division to:
- (a) develop, implement, and administer the tutorial and test described in this section; and
- (b) fulfill the other duties imposed on the division under this part.

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- (6) The division may make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:
- (a) develop, implement, and administer the tutorial and test described in this section; and
- (b) fulfill the other duties imposed on the division under this part.
- (7) The Department of Health shall assist the division in developing the portion of the test described in Subsection (1)(d).

Amended by Chapter 318, 2018 General Session

Part 5

Costs and Funding

58-37f-501 Costs of operating database and recording and submitting data.

- (1) All department and division costs necessary to establish and operate the database shall be funded by appropriations from:
- (a) the Commerce Service Account; and
- (b) the General Fund.
- (2) All costs associated with recording and submitting data as required in this chapter shall be assumed by the submitting pharmacy.

Amended by Chapter 287, 2010 General Session, (Coordination Clause)

Enacted by Chapter 287, 2010 General Session

58-37f-502 Use of dedicated credits -- Controlled Substance Database -- Collection of penalties.

- (1) The director may use the money deposited in the General Fund as a dedicated credit under Subsections 58-37-6(8)(a), 58-37f-601(3)(d), and 58-37f-602(2) for the following purposes:
- (a) maintenance and replacement of the database equipment, including hardware and software;
- (b) training of staff; and
- (c) pursuit of external grants and matching funds.
- (2) The director of the division may collect any penalty imposed under Subsections 58-37-6(8)(a), 58-37f-601(3)(d), and 58-37f-602(2) and which is not paid by:
- (a) referring the matter to the Office of State Debt Collection or a collection agency; or
- (b) bringing an action in the district court of the county in which the person owing the debt resides or in the county where the office of the director is located.
- (3) The director may seek legal assistance from the attorney general or the county or district attorney of the district in which the action is brought to collect the fine.
- (4) The court shall award reasonable attorney fees and costs to the division for successful collection actions under Subsection (2)(b).

Renumbered and Amended by Chapter 287, 2010 General Session

Amended by Chapter 391, 2010 General Session

Part 6

Penalties

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58-37f-601 Unlawful release or use of database information -- Criminal and civil penalties.

(1)

- (a) Any person who knowingly and intentionally releases:
- (i) any information in the database or any information obtained from other state or federal prescription monitoring programs by means of the database in violation of the limitations under Part 3, Access and Utilization, is guilty of a third degree felony; or

- (ii) any information in the database accessed under Section 58-37f-303 by an electronic data system, or accessed by a person via an electronic data system, in violation of rules established by the division under Subsection 58-37f-303(4) is guilty of a third degree felony.
- (b) Any person who negligently or recklessly releases:
- (i) any information in the database or any information obtained from other state or federal prescription monitoring programs by means of the database in violation of the limitations under Part 3, Access and Utilization, is guilty of a class C misdemeanor; or
- (ii) any information in the database accessed under Section 58-37f-303 by an electronic data system, or accessed by a person via an electronic data system, in violation of rules established by the division under Subsection 58-37f-303(4) is guilty of a class C misdemeanor.

(2)

- (a) Any person who obtains or attempts to obtain the following by misrepresentation or fraud is guilty of a third degree felony:
- (i) information from the database;
- (ii) information from any other state or federal prescription monitoring program by means of the database; or
- (iii) information from the database or any other state or federal prescription monitoring program via an electronic data system under Section 58-37f-303.
- (b) Any person who obtains or attempts to obtain information from the database, including via an electronic data system under Section 58-37f-303 that has access to the database, for a purpose other than a purpose authorized by this chapter or by rule is guilty of a third degree felony.

(3)

- (a) Except as provided in Subsection (3)(e), a person may not knowingly and intentionally use, release, publish, or otherwise make available to any other person the following information for any purpose other than those specified in Part 3, Access and Utilization:
- (i) information obtained from the database;
- (ii) information obtained from any other state or federal prescription monitoring program by

means of the database; or

- (iii) information in the database accessed under Section 58-37f-303 by:
- (A) an electronic data system; or
- (B) a person via an electronic data system.
- (b) Each separate violation of this Subsection (3) is a third degree felony and is also subject to a civil penalty not to exceed \$5,000.
- (c) The procedure for determining a civil violation of this Subsection (3) is in accordance with Section 58-1-108, regarding adjudicative proceedings within the division.
- (d) Civil penalties assessed under this Subsection (3) shall be deposited in the General Fund as a dedicated credit to be used by the division under Subsection 58-37f-502(1).
- (e) This Subsection (3) does not prohibit a person who obtains information from the database under Subsection 58-37f-301(2) (h), (i), (k), or (4)(c) from:

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- (i) including the information in the person's medical chart or file for access by a person authorized to review the medical chart or file; or
- (ii) providing the information to a person in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996.

Amended by Chapter 112, 2016 General Session

Amended by Chapter 238, 2016 General Session

 ${\bf 58\text{-}37f\text{-}602}\ Failure\ by\ pharmacist\ to\ submit\ information\ -\text{-}\ Penalties.$

- (1) The failure of a pharmacist-in-charge, a pharmacy, or a third party under contract with a pharmacist-in-charge to submit information to the database in accordance with the requirements of Section 58-37f-203, after the division has submitted a specific written request for the information or when the division determines the pharmacist-in-charge, pharmacy, or third party has a demonstrable pattern of failing to submit the information as required, is grounds for the division to take the following actions in accordance with Section 58-1-401:
- (a) refuse to issue a license to the pharmacist-in-charge or the pharmacy;
- (b) refuse to renew the license of the pharmacist-in-charge or the pharmacy;

- (c) revoke, suspend, restrict, or place on probation the license of the pharmacist-in-charge or the pharmacy;
- (d) issue a public reprimand to the pharmacist-in-charge or the pharmacy;
- (e) issue a cease and desist order to the pharmacist-in-charge, the pharmacy, or the third party; and
- (f) impose a civil penalty on the pharmacist-in-charge, the pharmacy, or the third party of up to \$1,000 for each dispensed prescription regarding which the required information is not submitted in accordance with the requirements of Section 58-37f-203.
- (2) Civil penalties assessed under Subsection (1)(f) shall be deposited in the General Fund as a dedicated credit to be used by the division under Subsection 58-37f-502(1).
- (3) The procedure for determining a civil violation of this section shall be in accordance with Section 58-1-108, regarding adjudicative proceedings within the division.

Amended by Chapter 123, 2018 General Session

Part 7

Miscellaneous

58-37f-701 Immunity from liability.

- (1) An individual who has submitted information to or accessed and reviewed the database in accordance with this chapter may not be held civilly liable, including under Title 78B, Chapter 3, Part 4, Utah Health Care Malpractice Act, for such actions, or a lack of action, which are
- protected and are not subject to civil discovery, as provided in Section 58-37f-302.

 (2) Nothing in Section 58-37f-304 establishes a minimum standard of care for prescribers and

Amended by Chapter 327, 2018 General Session

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dispensers.

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58-37f-702 Reporting prescribed controlled substance poisoning or overdose to a practitioner.

(1)

(a) The division shall take the actions described in Subsection (1)(b) if the division receives a

report from a general acute hospital under Section 26-21-26 regarding admission to a general acute hospital for poisoning or overdose involving a prescribed controlled substance.

- (b) The division shall, within three business days after the day on which a report in Subsection (1)
- (a) is received:
- (i) attempt to identify, through the database, each practitioner who may have prescribed the controlled substance to the patient; and
- (ii) provide each practitioner identified under Subsection (1)(a) with:
- (A) a copy of the report provided by the general acute hospital under Section 26-21-26; and
- (B) the information obtained from the database that led the division to determine that the practitioner receiving the information may have prescribed the controlled substance to the person named in the report.

(2)

- (a) When the division receives a report from the medical examiner under Section 26-4-10.5 regarding a death caused by poisoning or overdose involving a prescribed controlled substance, for each practitioner identified by the medical examiner under Subsection 26-4-10.5(1)(c), the division:
- (i) shall, within five business days after the day on which the division receives the report, provide the practitioner with a copy of the report; and
- (ii) may offer the practitioner an educational visit to review the report.
- (b) A practitioner may decline an educational visit described in Subsection (2)(a)(ii).
- (c) The division may not use, in a licensing investigation or action by the division:
- (i) information from an educational visit described in Subsection (2)(a)(ii); or
- (ii) a practitioner's decision to decline an educational visit described in Subsection (2)(a)(ii).
- (3) It is the intent of the Legislature that the information provided under Subsection (1) or (2) is provided for the purpose of assisting the practitioner in:
- (a) discussing with the patient or others issues relating to the poisoning or overdose;
- (b) advising the patient or others of measures that may be taken to avoid a future poisoning or overdose; and
- (c) making decisions regarding future prescriptions written for the patient or others.

- (4) Any record created by the division as a result of an educational visit described in Subsection (2) (a)(ii) is a protected record for purposes of Title 63G, Chapter 2, Government Records Access
- and Management Act.
- (5) Beginning on July 1, 2010, the division shall, in accordance with Section 63J-1-504, increase the licensing fee described in Subsection 58-37-6(1)(b) to pay the startup and ongoing costs of the division for complying with the requirements of this section.

Amended by Chapter 128, 2019 General Session

58-37f-703 Entering certain convictions into the database and reporting them to practitioners.

(1) When the division receives a report from a court under Subsection 41-6a-502(4) or 41-6a-502.5(5)(b) relating to a conviction for driving under the influence of, or while impaired by, a prescribed controlled substance, the division shall:

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- (a) daily enter into the database the information supplied in the report, including the date on which the person was convicted;
- (b) attempt to identify, through the database, each practitioner who may have prescribed the controlled substance to the convicted person; and
- (c) provide each practitioner identified under Subsection (1)(b) with:
- (i) a copy of the information provided by the court; and
- (ii) the information obtained from the database that led the division to determine that the practitioner receiving the information may have prescribed the controlled substance to the convicted person.
- (2) It is the intent of the Legislature that the information provided under Subsection (1)(b) is provided for the purpose of assisting the practitioner in:
- (a) discussing the manner in which the controlled substance may impact the convicted person's driving;
- (b) advising the convicted person on measures that may be taken to avoid adverse impacts of the controlled substance on future driving; and

- (c) making decisions regarding future prescriptions written for the convicted person.
- (3) Beginning on July 1, 2010, the division shall, in accordance with Section 63J-1-504, increase the licensing fee described in Subsection 58-37-6(1)(b) to pay the startup and ongoing costs of the division for complying with the requirements of this section.

Amended by Chapter 99, 2016 General Session

58-37f-704 Entering certain convictions into the database.

Beginning October 1, 2016, if the division receives a report from a court under Subsection 58-37-8(1)(e) or 58-37-8(2)(j), the division shall daily enter into the database the information supplied in the report.

Enacted by Chapter 99, 2016 General Session